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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/606,910

06/29/2000

Uwe Karsten

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/606,910	Applicant(s) KARSTEN ET AL.	
Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 February 2006 and 27 March 2006.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 27-37 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 27-29, 31 and 32 is/are allowed.
- 6) Claim(s) 30, 35 and 37 is/are rejected.
- 7) Claim(s) 33, 34 and 36 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 February 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date, _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 21, 2006, has been entered.

1. The amendment filed February 21, 2006, is acknowledged and has been entered. Claims 8-13 and 15-18 have been canceled. Claims 27-37 have been added.
2. Claims 27-37 are pending in the application and are currently under prosecution.
3. Claims 25-27 have not been entered.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

5. Applicant's claim under 35 USC § 119 for benefit of the earlier filing date of PCT Application No. PCT/DE98/03819, filed December 30, 1998, which claims benefit of the German priority document 197 98 400.4 (30 December 1997), is acknowledged.

However, claims 30, 35, and 37 do not properly benefit by the earlier filing date of German priority document 197 98 400.4 because the document fails to provide written support for the language of claims 30, 35, and 37. In particular, the foreign priority document does not describe a synthetic peptide consisting of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein the threonine of SEQ ID NO: 3 is

Art Unit: 1643

glycosylated with any member of a genus of "oligosaccharides". In addition, the foreign priority document does not describe a synthetic peptide consisting of at least one tandem repeat of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein the threonine residue of at least one occurrence of the amino acid sequence of SEQ ID NO: 3 is glycosylated.

Accordingly, the effective filing date of claim 37 is deemed the filing date of the instant application, namely June 29, 2000.

Grounds of Rejection Withdrawn

6. Unless specifically reiterated below, Applicant's amendment filed February 21, 2006, and/or the accompanying arguments have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed March 3, 2005.

Response to Arguments

7. Applicant's arguments with respect to the grounds of rejection set forth in the preceding Office action have been considered but are moot in view of the new ground(s) of rejection set forth below.

Grounds of Objection Maintained

Specification

8. As noted on the Notice of Non-Compliant Amendment, which was attached the preceding Office action mailed October 20, 2005, the amendment filed August 4, 2005 fails to meet the requirements of 37 C.F.R. § 1.121.

Until the a corrected amendment providing a compliant "Amendments to the Specification" section is provided, the disclosure is objected to for the reasons set forth in section 9 of the Office action March 3, 2005.

New Grounds of Objection

Claims

9. Claims 33, 34, and 36 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 28, 29, and 31. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

10. Applicant is advised that should claim 30 be found allowable, claim 35 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

New Grounds of Rejection

Claim Rejections – 35 USC § 112

11. Claims 30, 35, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a “new matter” rejection.

(a) Claims 30 and 35 are directed to a synthetic peptide consisting of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein the threonine of SEQ ID NO: 3 is glycosylated with any member of a genus of “oligosaccharides”.

At page 5 of the amendment filed February 21, 2006, Applicant has asserted that support for claims 30 and 35 is found in the specification, as originally filed, at page 3, line 17.

Art Unit: 1643

Contrary to Applicant's assertion, the specification, including the claims, as originally filed, does not appear to provide written support for the language of claims 30 and 35 because it does not describe the glycosylation of threonine by any member of a genus of "oligosaccharides".

Instead, the specification describes this glycosyl residue as a "monosaccharide", α -N-acetylgalactosamine (GalNAc), a "short-chained oligosaccharide", or the disaccharide Gal β -1,3GalNAc; see page 3, lines 16-18.

This disclosure is deemed insufficient to provide support for the language of the claims at least inasmuch as it does not describe the glycosylation of threonine by "long-chained oligosaccharides" or "intermediate-chained oligosaccharides", which are longer than "short-chained oligosaccharides" but shorter than "long-chained oligosaccharides".

This issue might be resolved if Applicant were to point to other specific disclosures in the specification, including the claims, as originally filed, which are believed to provide the necessary written support.

(b) Claim 37 is drawn to a synthetic peptide consisting of at least one tandem repeat of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein the threonine of at least one occurrence of the amino acid sequence of SEQ ID NO: 3 is glycosylated.

At page 5 of the amendment filed February 21, 2006, Applicant has asserted that support for claim 37 is found in the specification, as originally filed, at page 3, lines 14-16.

Contrary to Applicant's assertion, the specification, including the claims, as originally filed, does not appear to provide written support for the language of claim 37 because it does not describe a synthetic peptide consisting of more than one tandem repeat consisting of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein the threonine of *at least one, but not necessarily each occurrence* of the amino acid sequence of SEQ ID NO: 3 is glycosylated.

Art Unit: 1643

This issue might be resolved if Applicant were to point to other specific disclosures in the specification, including the claims, as originally filed, which are believed to provide the necessary written support.

Claim Rejections – 35 USC § 102

12. Claims 30, 35, and 37 are rejected under 35 U.S.C § 102(b), as being anticipated by Karsten et al. (*Cancer Res.* 1998 Jun 15; **58** (12): 2541-2549).

Claims 30 and 35 are drawn to a synthetic peptide consisting of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein the threonine of SEQ ID NO: 3 is glycosylated with any member of a genus of "oligosaccharides" (e.g., the disaccharide Gal β 1,3GalNAc).

Claim 37 is drawn to a synthetic peptide consisting of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein the threonine of the amino acid sequence of SEQ ID NO: 3 is glycosylated.

Karsten et al. teaches "MUC1 tandem repeat peptides", which consist of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2; see entire document (e.g., page 2542, Table 2). Karsten et al. teaches these synthetic peptides comprise SEQ ID NO: 3 and are glycosylated at the threonine residue of SEQ ID NO: 3; see, e.g., page 2542, Table 2. Karsten et al. teaches the peptides (e.g., peptides "A1" and "A12") are GalNAc- or Gal β 1,3GalNAc-glycosylated at the threonine residue of the amino acid SEQ ID NO: 3; see, e.g., page 2542, Table 2.

Claim Rejections – 35 USC § 103

13. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karsten et al. (*Cancer Res.* 1998 Jun 15; **58** (12): 2541-2549).

Here, claim 37 is drawn to a synthetic peptide consisting of more than one tandem repeat of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein the threonine of the amino acid sequence of SEQ ID NO: 3 is glycosylated.

Art Unit: 1643

Karsten et al. teaches that which is set forth above in the rejection of claim 37 under 35 U.S.C. § 102(b).

In addition, Karsten et al. teaches, “[a]nother question to be answered by further studies is whether both factors (length of the peptide and DTR glycosylation) might act synergistically with respect to their influence upon the immunogenicity of MUC1 peptides” (page 2549, column 1). Karsten et al. teaches synthetic peptide oligomers consisting of three, five, or six repeats of MUC1 tandem repeat domain; see, e.g., page 2542, column 2. Karsten et al. shows comparisons between these oligomers and either the glycosylated or non-glycosylated peptide monomer consisting of the amino acid sequence of a single MUC1 tandem repeat domain; see, e.g., page 2544, column 2. In general, the glycosylated monomer showed more activity than the oligomer, which, in turn, showed more activity than the non-glycosylated monomer; see, e.g., page 2544, column 2. However, Karsten et al. also shows that in most instances, the longer the length of the oligomers the greater the activity; see, e.g., page 2543, Table 4. It is for this reason that Karsten et al. suggests the aforementioned further studies to address the effects of both length and glycosylation.

Accordingly, it would have been *prima facie* obvious to one ordinarily skilled in the art at the time the invention was made to synthesize peptides consisting of at least two repeats of the amino acid sequence of the disclosed peptide monomers, which are glycosylated at the threonine in the same manner as the peptide monomer, so as to permit one to determine the effects of both length and glycoylation, because Karsten et al. suggests such further study be performed to determine if these factors might act synergistically with respect to their influence upon the immunogenicity of MUC1 peptides. Accordingly, one ordinarily skilled in the art at the time the invention was made would have been motivated to do so in order to perform such further studies and determine if both factors (length of the peptide and DTR glycosylation) might act synergistically with respect to their influence upon the immunogenicity of MUC1 peptides.

Allowable Subject Matter

14. Claims 27-29, 31, and 32 are allowed because the prior art of record does not teach or fairly suggest synthetic peptides consisting of at least one tandem repeat of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein the threonine of the amino acid sequence of SEQ ID NO: 3 is glycosylated.


Conclusion

15. Claims 30 and 33-37 are not allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
May 23, 2006